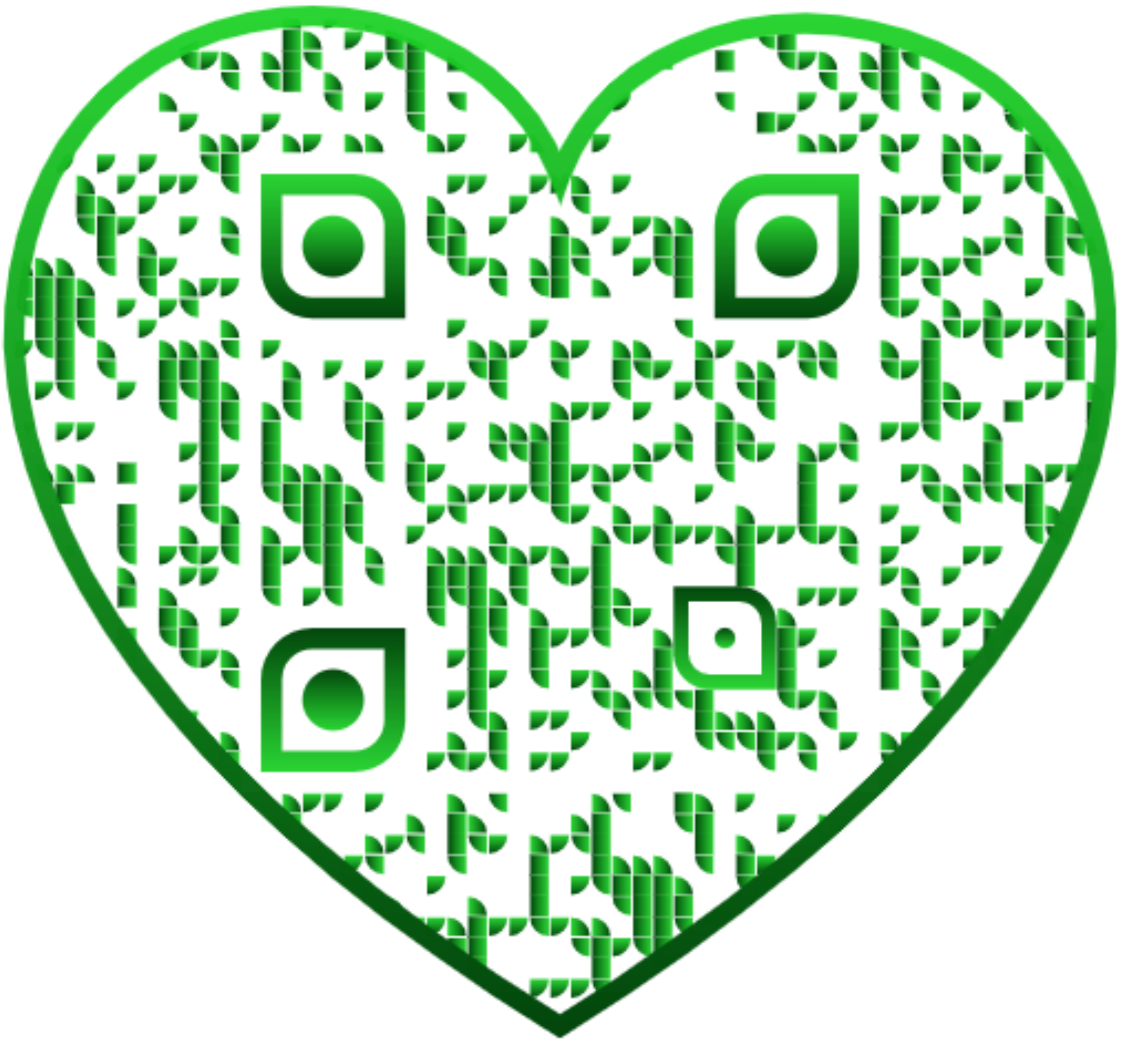
Laws Governing Practice of Pharmacy

October 4, 2021



Terms to remember

- **Law** : is the system of rules of conduct established by the government of a society to maintain stability and justice.
- **Ethics** : Ethics, or moral philosophy, is the branch of philosophy that involves systematizing, defending, and recommending concepts of right and wrong conduct.
- **Morals:** Morals are a person's ideas about right and wrong.
- **Values:** Values are principles of worth and are importance.
- **Moral principles:** the principles of right and wrong that are accepted by an individual or a social group.

Terms to remember Cont…

- **Pharmaceutical Jurisprudence** : It means study of fundamental laws relating to pharmacy.
- Pharmaceutical jurisprudence is a branch of pharmacy, which deals with various legislations pertaining to drugs and pharmaceuticals and profession of pharmacy.
- **Legislation:** A group of laws that have the force of authority by virtue of their promulgation by an official organ of a state or other organization.

Law vs Ethics

LAW	ETHICS
Laws are rules of behaviour sanctioned by governments that illustrate what people can or cannot do in their workplace. i.e. Simply, Law is something you must obey. ***Example:*** a pharmacist must be on the premises at all times and oversee all medicines being dispensed and sold.	Ethics means the ability to judge between *right* or *wrong* and good or bad actions. i.e. ethics is how society expects you to behave.

The Basis of Pharmacy Law

- The law is both a body of information and a system
  - used to resolve conflicts and preserve order within society.
- Pharmacy law
  - The law defines a set of responsibilities for pharmacists.
  - The law also provides a mechanism through which adverse outcomes are reviewed.
- As health professionals, Pharmacists are highly regulated because the slightest misstep in drug distribution or pharmaceutical care could cost a life.
- As a custodian of the nation's drug supply, pharmacists are subjected to extensive regulations.

Cont'd…

- Pharmacists study the law because through the law, society has described what is considered acceptable conduct for Pharmacists, and Pharmacists who fail to meet this level of acceptability will be held accountable for their failure.
- In most pharmacy practice situations, the question of "What is legal?" can be addressed by answering the question "What is best for the patient?

The Purpose of Pharmacy Law

- It protects patients from harm
  - Some pharmacy laws relate to all drugs and the hazards of using them for therapeutic reasons.
  - Other laws relate to a subset of drugs that have the potential for abuse.

The Structure of Pharmacy Law

- Pharmacy is regulated at the federal and state levels.
- Federal rules primarily relate to the drug product.
- State rules primarily relate to the people who practice pharmacy and the practice sites with in which they perform their professional duties.
- At both levels there are administrative agencies, legislatures, and court.

The Structure of Pharmacy Law…

- Administrative agencies:
  - regional health bureau, at the state level, and
  - the food, medicine and health care administration control authority at the federal level,
    - make rules for pharmacists
    - they enforce their own rules as well as rules made by the state and federal legislatures.

History of Pharmacy Law

- The main reason for all pharmacy drug laws in this world is protection of the public.
- Before regulation, drug products routinely contained narcotics such as opium, morphine, heroin, and cocaine. Information provided in the labeling was limited.
- The labeling frequently omitted any listing of active and inactive ingredients; warnings about habit-forming drug products; information about misuse or improper use of the drug product; directions for use and dosage recommendations.
- Statements that products would "cure disease" were routinely contained in the labeling information.
- Many products were contaminated. As unacceptable results became evident, public safety became a major concern.

Laws Governing Practice of Pharmacy

- Many countries have different laws governing pharmaceuticals.
- Major laws that govern the practice of pharmacy are:-
  - Food, drug and cosmetic Act
  - Controlled substances Act
  - Poisons Act/poison prevention packaging Act
  - Tort law
  - Commercial law

1. Food, drug and cosmetic Act (FDCA) of 1938

- In 1906, the U.S government enacted the pure food & Drug Act
  - This was the first attempt by the U.S to control the quality of drug
  - This act prevented the manufacture, sale, or transportation of adulterated, misbranded, poisonous, or deleterious foods, drugs, medicines and liquors in interstate commerce.

FDCA of 1938 Cont'd…

- FDCA is an amendment of the pure food and Drug Act.
- The amendment of FDCA was triggered by the event called, "Sulphanilamide elixir tragedy" in 1937
- Sulfanilamide was an anti-infective sulfa drug.
- The manufacturer developed an elixir using diethylene glycol as the solvent. No toxicity tests were performed on the diethylene glycol.
- Today, diethylene glycol is used as an industrial solvent. The deaths resulted from the solvent in the elixir.

FDCA of 1938 Cont'd…

- In 1937, the FDA had no authority to ban the use of any unsafe drug products.
- In order to remove the drug product from the market, the FDA claimed that the drug was misbranded because it was labeled as an elixir.
- By definition, an elixir had to contain alcohol and this drug product did not contain alcohol.

FDCA of 1938 Cont'd…

- The FDCA was targeted at drug safety.
- Forms the basis of today's drug regulation.
- The law required that new drugs be shown to be safe prior to their marketing.
- Several subsequent amendments have added requirements to the FDCA

- Durham-Humphrey Amendment of FDCA(DHA FDCA) of the 1951:-
  - provided the basis for categorizing drugs as prescription only and non-prescription drugs(OTC).
  - requires that prescription only drugs should be *labeled* as "Law prohibits dispensing without prescription".

FDCA of 1938 Cont'd…

- Accordingly, a drug will be PO if:
  - It is habit forming,
  - It is not safe for self medication ,
  - It is a new drug that has not been proved to be safe.
- In 1952, the prescription-only requirement became effective, creating two classes of drugs:
  - those available without a prescription and
  - those available only with a prescription.

FDCA of 1938 Cont'd…

- non-prescription drugs must bear a seven point label:
  - name of the product
  - name & address of the manufacturer, packer or distributor
  - net contents of the package
  - name & quantity of all ingredients
  - Cautions & warnings needed for the protection of the user
  - Adequate directions for safe & effective use
  - name of any habit forming drug contained in the preparation

FDCA of 1938 Cont'd…

- In 1961, an amendment
  - required proof of efficacy, in addition to safety, prior to marketing of a new drug.
- The 1984 amendment
  - made is easier to market generic equivalents of drugs, but granted patent term extension to the innovators of new drugs, under certain conditions.

FDCA of 1938 Cont'd…

- In general FDCA and its amendments are designed to prevent two evils:
  - adulteration and misbranding
- Adulteration – the composition of the product
- Misbranding – labeling violations

Adulteration

- consists in whole or in part any faulty or decomposed substance.
- prepared, packed or held under insanitary condition
- manufactured, processed, packed or held under conditions that don't comply with the FDA's GMP regulations
- Its container is composed of any poisonous or deleterious substance that may render the drug injurious to health.
- its strength differs from its labeled strength
- fail to meet compendia standards

Misbranding

- labeling is false or misleading in any particular
- label doesn't bear the name & address of the manufacturer, or distributor as well as an accurate statement of the quantity of the contents.
- contains a habit-forming substance specified in the regulations & doesn't bear the statement warning "May be habit-forming" directly adjacent to the name of the agent.
- labeling doesn't bear adequate directions for use & is not in accordance with compendia standards.
- was manufactured or processed in a plant that was not registered with the PLEA

2. Controlled Substance Act (Narcotic Drugs and Psychotropic Substances)

Controlled Substance Ac(CSA)

- What are controlled substances?

Answer:

- Any drug subject to control according to Narcotic Drugs conventions of the United Nations.
- Substances of high abuse potential.

- Why we need drug control?(Discussion)

Answer:

- To assure that drugs intended for medical use are not diverted to nonmedical uses.

Controlled Substance Ac(CSA)…

- Controlled Substance Act of 1970 reduced drug abuse by defined certain legal and illegal acts pertaining to these substances use.
- enacted by US congress in1971
- the legal basis by which the management of drugs/substances that have the potential for physical & psychological dependence and abuse are regulated
- often determines under which schedule it will be controlled

Schedules of controlled substances

- The act ranked controlled substances into five categories, or schedules:
  - ranging from those with great potential for abuse (Schedule I) to those with little such potential (Schedule V).
- Schedules Based on criteria:
  - Potential for abuse or addiction
  - Medical use
- Schedule of drug determines level of control.
- Narcotics are most highly regulated.

Schedules of controlled substances…

- **Schedule I (CI)**
  - high potential for abuse
  - most restrictive
  - Research use only
  - No acceptable medical use/not available in pharmacy
  - Examples: Marijuana, peyote, mescaline, heroin
- **Schedule II (CII)**
  - high potential for abuse or misuse
  - high risk of dependence
  - Dispensing severely restricted

Schedules of controlled substances…

- Requires written prescription
- No refills on script
- Abuse may lead to severe addiction

- Examples: Oxymorphone, Morphine, meperidine, Methadone, amobarbital, pentobarbital, cocaine, codien, amphetamine, oxycodone, methylphenidate etc.

❑ Schedule II (CII)

- Moderate or less than C-I & C-II potential for abuse, misuse & dependence.
- written script, up to 5 refills in 6 months.
- Examples: Nalorphine, benzephatamine, anabolic steriod, etc

Schedules of controlled substances...

- Also includes combination drug products:
  - acetaminophen and codeine
  - acetaminophen with hydrocodone

Schedule IV (CIV)

- low potential for abuse & limited risk of dependence
- written scripts with 5 refills in 6 months.
- Abuse may lead to limited dependence.
- Examples: Diazapam, Lorazepam, Alprazolam, Midazolam, Temazepam, Clonazepam, phenobarbital, & other sedatives and hypnotics.

Schedules of controlled substances…

- **Schedule IV (CIV)**
  - lowest potential for abuse, misuse, or dependence
  - Some sold w/o a prescription
  - examples: cough medications with limited amount of liquid codeine, anti- diarrheal medications containing limited amount of opiate, such as diphenoxylate/atropine.

Refills of Controlled Drugs

- Schedule III & IV prescriptions
  - refilled up to 5 times within 6 months
- Schedule V prescriptions
  - may be refilled more than 5 times
  - have 6 month time limit on refills
- Schedule II prescriptions – may not be refilled

Records for Controlled Meds

- Must maintain complete & accurate records for controlled substances
  - purchased, received, distributed, or dispensed
- Drug regulatory authority requires pharmacy to
  - keep controlled substance records for 2 years
  - have records readily available for inspection

Narcotic Drugs and Psychotropic Substances(NDPS) act

- An Act to consolidate and amend the law relating to narcotic drugs, to make stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances.
- This is a special Act, while adopting the liberal construction of the Act, it is found that the Act has been enacted with a view to make stringent provisions for the control and regulation of operations relating to the narcotic drugs and psychotropic substances.

Special License Requisite

- A special license issued by the Authority shall be required to import, export, manufacture or distribute narcotic drugs.

Import and Export of NDPS

1)Any person having a permanent special license to import or export NDPS shall apply for a special import or export permit for each delivery; such special permit shall be valid only for ninety (90) days.

2) No person shall import or export NDPS through post office or by ship.

3) No person shall import or export NDPS packing them with other drugs or articles.

Prescriptions of NDPS

1) Only a medical practitioner who is registered and have a special license shall prescribe NDPS.
2) No medical practitioner shall prescribe narcotic drugs and psychotropic substances for himself.
3) Narcotic drugs and psychotropic substances shall only be prescribed on a special prescription paper.

Storage and Disposal

- NDPS and invoices, registers, and prescriptions shall be stored in a lockable metal cupboard or in a special room the key of which shall at all times remain in the hands of the authorized professional.
- Any person shall keep damaged, expired, or seized NDPS in a separate place and shall dispose them in accordance with the directive to be issued by the Authority pursuant to this Proclamation.

3. Poisons Act (poison prevention packaging Act)

- enacted in 1970 to establish standards for child resistant packaging.
- considers all PO & some non-prescription medications as hazardous substances – must be dispensed with child resistant closures.

❑ What is poison?

✓ "***Poison***" means any substance that may cause danger to human, animal, plant or environment even when taken in a small quantity; (According to FMHACA)

Poisons Act Cont…

- There are number of controls on the sale, storage, labeling and other dealing with those poisons which are not medicines.
- Poisons act sets up a mechanism to specify substance as poison, and to lay down rules on how they are to be used.

Poison list

- The list consist of two parts:
  - **Part I** is a list of poison which can be only retailed from a pharmacy.
  - **Part II** is a list of poison which can be sold from either a pharmacy or listed seller.
- Generally, poison in part one must be sold:
  - By pharmacist or under supervision of pharmacist.
  - At the pharmacy
- Poisons in part II must be sold:
  - From a pharmacy or listed seller from his premises.
  - Regulation requires the manufacturer or distributor of a chemical to classify it according to its danger.

Regulations with respect to sale of poisons, radioactive pharmaceuticals and pesticides

- Without obtaining certificate of competence, no one should produce, import, export, distribute or sale poison or radiopharmaceuticals.

- We must have to keep records and submit reports to the appropriate organ on manufactured, imported, distributed or sold poisons or radio active pharmaceuticals

Regulations with respect to packaging of poison

- *Packaging*, *transportation*, *storage* & *distribution* of pesticides, poisons and radio active pharmaceuticals shall be in such a manner that minimizes danger to the life of human being, animals and the environment.
- The executive organ shall jointly work with the appropriate organ to ensure that the production, transportation, storage, usage and disposal of pesticides do not cause any health hazard.

Regulations with respect to labeling of poison

- *It shall not be lawful for a person to sell any poison unless the container of the poison is labeled* with:
  - The name of chemical/poison.
  - The name and address of supplier.
  - With the word "Poison" or other prescribed indication of the character of the substance.
  - The type of danger
  - Warning about use.

FMHACA - Proclamation

- FMHACA was established by proclamation to ensure the safety and quality of products and health services.
- FMHACA's mandates include the *registration*, *licensing* and *inspection* of health professionals, pharmaceuticals, food establishments and health institutions.
- Products controlled by FMHACA include *human* and *veterinary drugs*, *radiopharmaceuticals*, *traditional medicines*, *pesticides*, *medical supplies* and *instruments*, *sanitary items*, *cosmetics* and *raw & packaging materials*.

Legislation & Regulation in Ethiopia

- The pharmaceutical sector had been regulated by Pharmacy regulation No. 288/64 of 1964.
- This regulation has been replaced by the Drug Administration And Control Proclamation No. 176/99 of June 1999 which is comprehensive enough to regulate the entire life cycle of pharmaceuticals. This proclamation is currently replaced by FMHACA Proclamation No. 661/2009.
- Some of the laws were repealed include:
  a) the Drug Administration and Control Proclamation No. 176/1999; and
  b) the Public Health Proclamation No. 200/2000.

4. Tort Law

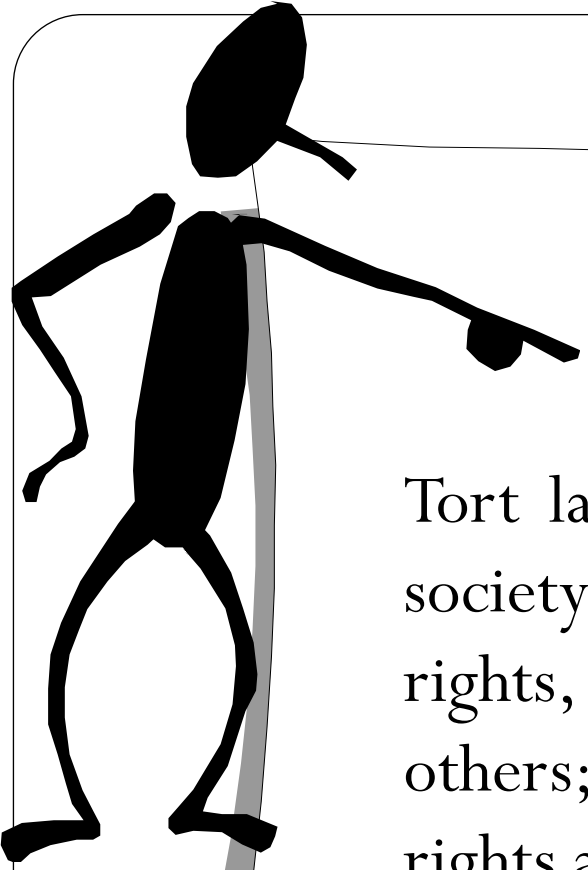
What is a tort??

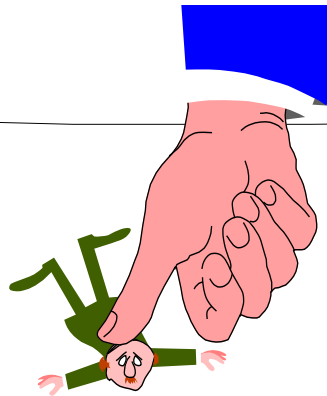
- **Tort** is the French word for a "***wrong***." (simply a civil wrong)
- A tort deals with a private wrong/injury committed by one person against another arising from a ***breach of duty.***
- ***Tort law*** protects a variety of injuries and provides remedies for them.
- Under tort law, an injured party can bring a ***civil lawsuit*** to seek compensation for a wrong done to the party or the party's property.

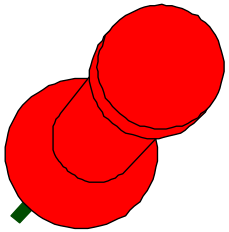
Crime vs Tort

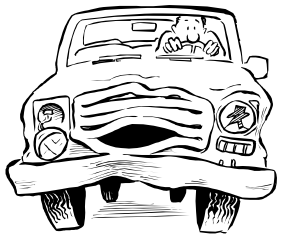
- A Crime is a wrong against the public at large.
- A tort is a wrong against an individual.
  - Criminal prosecutions are brought by the state or government.
  - Tort prosecutions are brought by the person wronged.
  - A person who commits a tort is called a tortfeasor.
    - A tort is one person's interference with another person's right's, either through intent, negligence or liability.

TORT LAW









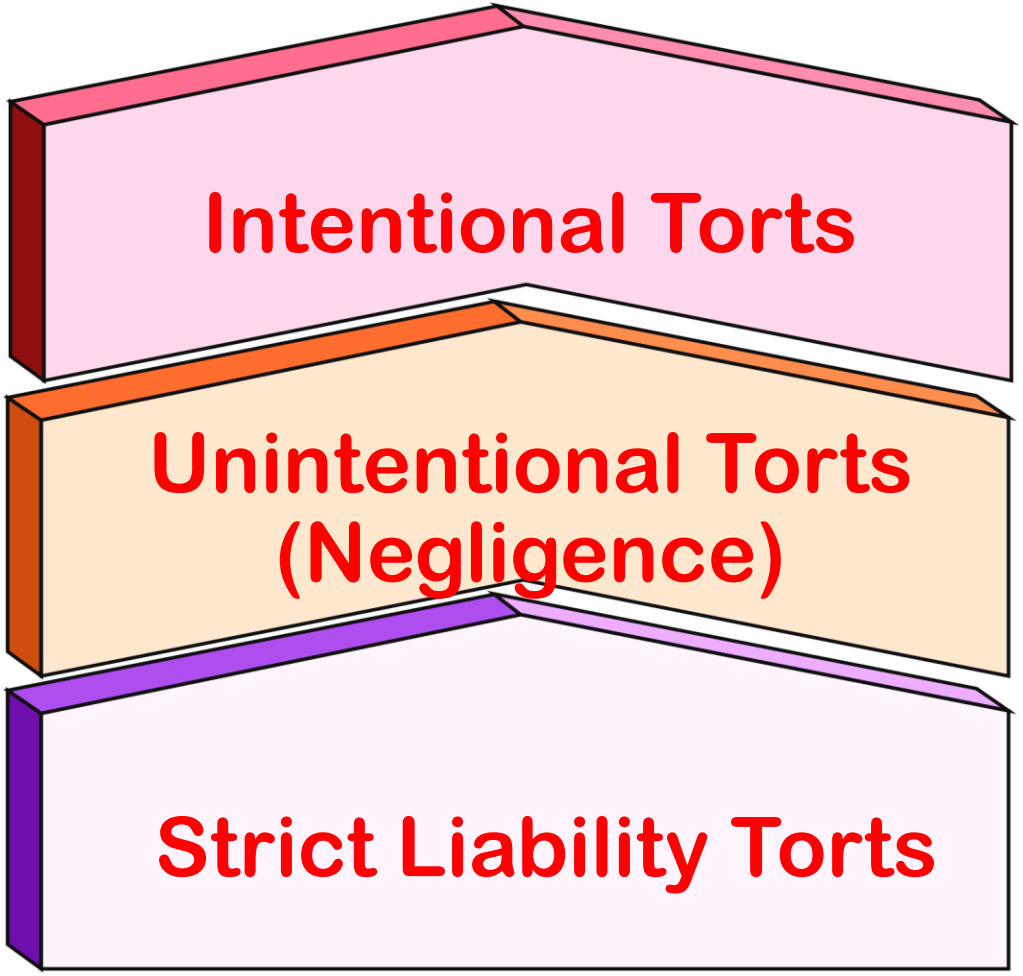
Tort law is based on the idea that everyone in our society has certain rights (Along with having certain rights, everyone has the duty to respond the rights of others; the purpose of tort law is to enforce those rights and duties)

Tort law imposes a duty on persons and business agents not to intentionally or negligently injure others in society.

Tort, Tort law & Tort damages

- Hence a tort is simply a civil wrong.
- The law of tort is defined as a body of rights, obligations and remedies that is applied by courts in civil proceedings to provide relief for individuals or victims (claimant or plaintiff) who have suffered harm from the wrongful acts of others (defendant or **tortfeaser**).
- Tort damages are monetary damages that are sought from the offending party.
- They are intended to compensate the injured party for the injury suffered.

Categories of Torts



A) Intentional Torts

- Intentional torts are those that are committed willfully against a person or property. The offender must intend to commit the act. The injured party may seek a civil case against the person who committed the tort against him or her.
- A category of torts that requires that the defendant possessed the intent to do the act that caused the plaintiff's injuries.
- There are two categories of intentional torts:
  - **Intentional torts against persons**
  - **Intentional torts against property**

Intentional Torts Against Persons

- The law protects a person from unauthorized touching, restraint, or other contact.
- The law also protects a person's reputation and privacy.
- Violations of these rights are actionable as torts.

Intentional Torts Against Persons cont…

- **Assault (Threat of violence)**
  - threats that results in fear or being touched in an offensive manner.
  - Intentional and unlawful threat of bodily harm to another
- **Battery (Completed assault)**
  - Unlawful, unprivileged(unwanted) and harmful or offensive physical contact with another person without his or her permission.
- **False imprisonment**
  - The intentional confinement or restraint of another person without authority or justification and without that person's consent.

Intentional Torts Against Persons cont…

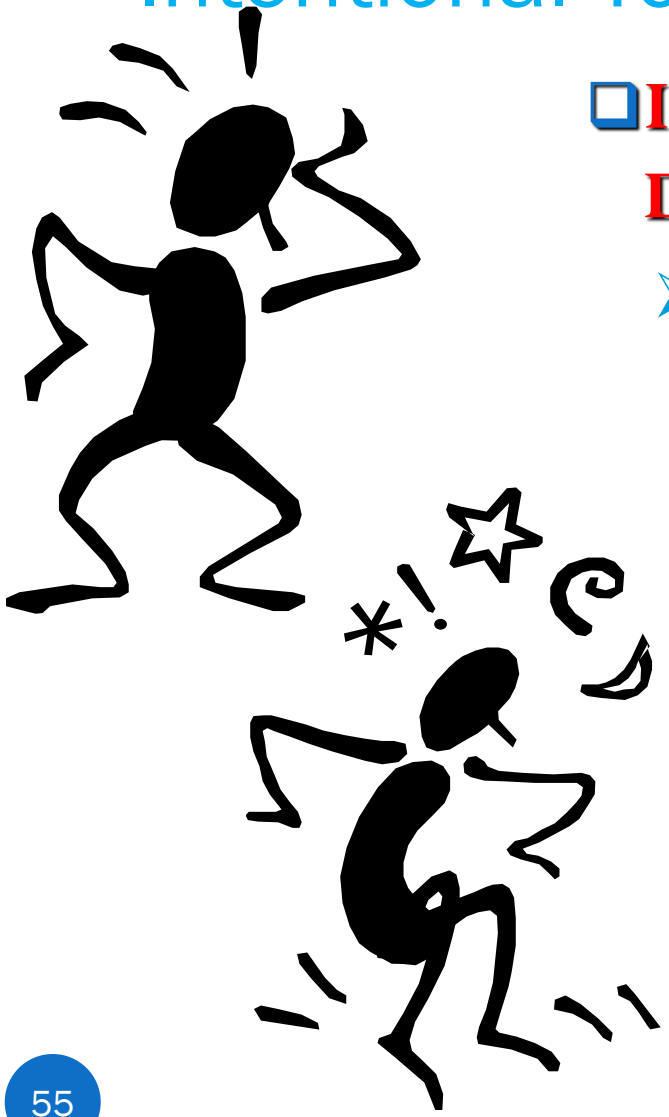
- **Defamation of Character**
  - Injuring another's reputation or False statement(s) made by one person about another.
  - **Slander –** verbal(oral defamation of character.)
  - **Libel –** Written(a false statement that appears in a letter, newspaper, magazine, book, photo, video, etc.)

Intentional Torts Against Persons cont…

Invasion of the Right to Privacy

- The oral or written dissemination of private information about an individual. Unauthorized release of confidential information.
- Example: a volunteer gives co-workers a patient's confidential health information without permission or privilege.

Intentional Torts Against Persons cont…



- **Intentional Infliction of Emotional Distress**
  - A tort that says a person whose *extreme and outrageous* conduct intentionally or recklessly causes severe emotional distress to another person is liable for that emotional distress. Also known as the tort of outrage.

Intentional Torts Against Property

- There are two general categories of property:
  - **Real Property** – consists of land and anything permanently attached to that land.
  - **Personal Property** – consist of things that are movable.
    - ✓ Automobiles
    - ✓ Books
    - ✓ Clothes

Intentional Torts Against Property cont..

- **Trespass to Land**
  - A tort that interferes with an owner's right to exclusive possession of land.
- **Trespass to Personal Property**
  - A tort that occurs whenever one person injures another person's personal property; or
  - Wrongful injury or Interference with that person's enjoyment of his or her personal property.

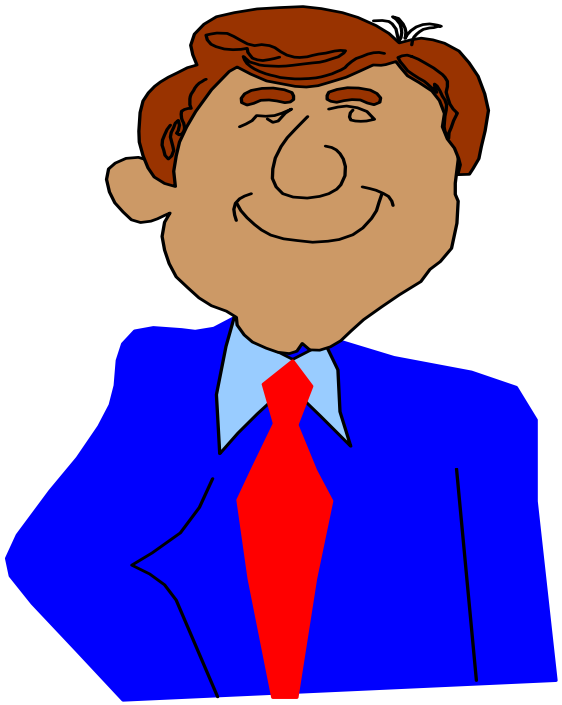
Intentional Torts Against Property cont..

Conversion of Personal Property

- A tort that deprives a true owner of the use and enjoyment of his or her personal property by:
  - Taking over such property; and
  - Exercising ownership rights over it.

B) Unintentional Torts

Unintentional Tort

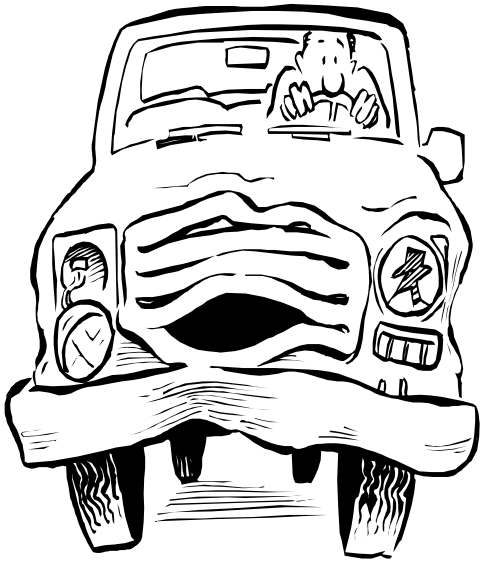


- A doctrine that says a person is liable for harm that is the foreseeable consequence of his or her actions. Also known as **Negligence**.

Unintentional Torts (Negligence) (continued)

Negligence

- The omission to do something which a reasonable person would do; or
- Doing something which a prudent and reasonable man would not do.
- Most torts of pharmacists are negligent torts.



Unintentional Torts (Negligence) (continued)

- To be successful in a negligence lawsuit, the plaintiff must prove that:
  1. The defendant owed a ***duty of care*** to the plaintiff
  2. The defendant acted in ***breach of duty***.
  3. The plaintiff suffered ***actual harm*** or ***injury.***
  4. The defendant's ***negligent act(breach of duty)*** was ***proximate cause*** of plaintiff's injury.

Unintentional Torts (Negligence) (continued)

- A legal cause of action for negligence has **4** elements: all must be proven
    a) Duty of care
    b) Breach of duty
    c) Damage/Harm/Injury
    d) Causation.

Unintentional Torts (Negligence) (continued)

a) **Duty of Care –** the obligation we all each other not to cause any unreasonable harm or risk of harm.

- It is establishing the presence of a duty owed by one person to another.
- Each unique personal injury claim starts with identifying this duty.
- Pharmacists have a duty to provide patients with the best care possible.
  - duty to ensure that medications are prescribed appropriately and that patients understand potential side effects.

Unintentional Torts (Negligence) (continued)

b) **Breach of Duty –** a failure to exercise reasonable care or to act as a reasonable person would act.

- Breach of duty, for example, may be in the form of:

Dispensing Errors:	i) A pharmacist who fills a prescription in a way other than it was ordered by the prescriber has breached a duty.
	ii) If the error is b/c of eligible hand writing?
	iii) A pharmacist who substituted a generic drug product for a brand name product in a way that is not permitted by law had breached the duty of care if the patient was harmed b/c of the **bioinequivalence** of the two drugs.

Unintentional Torts (Negligence) (continued)

c) **Damage/Injury to Plaintiff –** the plaintiff must suffer personal injury or damage to his or her property to recover monetary damages for the defendant's negligence.

- This element is closely tied to each of the three elements.
- The damage can be ***Actual*** or ***Economic.***

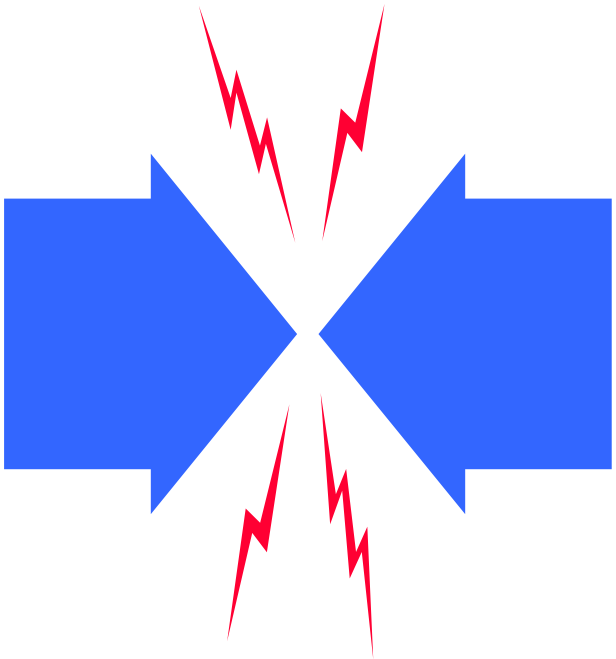
Actual Damages	*Economic Damages*
Nonmonetary losses, including : ✓ emotional injury - "pain and suffering" ✓ disability or disfigurement …	✓ Financial loss ✓ medical expenses ✓ lost wages ✓ loss of employment…

Unintentional Torts (Negligence) (continued)

d) **Causation –** is when the breach of duty becomes the direct cause of another person's injuries.

- Simply it tells us, something that produces a result that otherwise would not have occurred.
- a person who commits a negligent act is not liable unless his or her act was the cause of the plaintiff's injuries.
  - **Causation in Fact** (actual cause)
  - **Proximate Cause** (legal cause)

Unintentional Torts (Negligence) (continued)



- **Causation in Fact** (actual cause)
  - The actual cause of negligence.
  - A person who commits a negligent act is not liable unless causation in fact can be proven.

Unintentional Torts (Negligence) (continued)

- **Proximate Cause** (legal cause)
  - Under the law, a negligent party is not necessarily liable for all damages set in motion by his or her negligent act.
  - The law establishes a point along the damage chain after which the negligent party is no longer legally responsible for the consequences of his or her actions.

Unintentional Torts (Negligence) (continued)

- Even if a pharmacist breached his duty, malpractice under the law requires proof that the pharmacists misconduct caused the damage

- The type and severity of injuries must be related to a failure to act in a reasonable way.

Defences to Negligence

- Even if the plaintiff can proof the 4 elements of an action for negligence, the defendant may be able to prove affirmative defenses that will free him/her.

I. **Contributory negligence**
   - If the plaintiff could have avoided the consequences of the defendant's negligence by ordinary care, then there is no recovery under the defense of contributory negligence.
   - When the plaintiff's own negligence helped cause the harm.
   - The pharmacist will not be liable.

II. **Comparative negligence-** Negligence of both parties are compared.
   - Plaintiff's recovery equal to his percent of negligence.
   - damages awarded are reduced by the degree of negligence that plaintiff contributed to the harm.

C) Strict Liability

- Strict liability is liability without fault.
- A participant in a covered activity will be held liable for any injuries caused by the activity even if he or she was not negligent.
- Negligence does not apply.
- There are certain ultra hazardous activities that can place the public at risk of injury even if reasonable care is taken; and
- The public should have some means of compensation if such injury occurs.
  - Example:- using explosives(fireworks), storing flammable liquids in highly populated areas, and product liability in most cases.

5. Commercial Law

- Also known as business law, is the body of law that applies to the ***rights***, ***relations***, and ***conduct*** of persons and ***businesses engaged*** in commerce, merchandising, trade, and sales.
- It is often considered to be a branch of civil law and deals with issues of both private law & public law.
- Overall the term 'Commercial law' describes a wide body of laws that **govern business transactions**.

Business law & Commercial law

- ***Business law*** and ***commercial law*** are two areas of legal practice that have so *many* ***overlapping*** *issues* that most attorneys who practice one will also have expertise in the other.
- **Commercial law** focuses on ***the sale and distribution of goods, as well as financing of certain transactions***.
- **Business law** focuses on the other aspects of business, including ***forming a company, mergers and acquisitions, shareholder rights, and property issues such as leasing office or warehouse space***.
- A business that sells products will almost certainly need a **lawyer** with experience in both of these fields. ***Business law is regulated by both state and federal law.***
- Today in Ethiopia, the development of commerce has outgrown the provision of the laws relating to Business organizations and bankruptcy. The commercial life of Ethiopia has expanded, increasing numbers of Ethiopian and foreign company have been developed and registered, and more complex methods of transacting business have been developed in recent years.

Thank you!